NIH Policy on Informed Consent for Human Fetal Tissue Research

Notice Number: NOT-OD-16-033

Key Dates

Release Date: February 11, 2016

Related Announcements NOT-OD-15-143

Issued by National Institutes of Health (NIH)

Purpose

The National Institutes of Health (NIH) is committed to ensuring that research involving human fetal tissue is conducted responsibly and meets the highest ethical standards. The purpose of this guide notice is to inform NIH-funded grantees and contractors of certain expectations when conducting human fetal tissue research. NIH-funded research involving human fetal tissue must be conducted in compliance with all applicable federal, state, and local laws and regulations (for more details see Guide Notice NIH-NOT-OD-15-143). Current federal laws and regulations require informed consent for research involving the transplantation of human fetal tissue and for research with human fetal material associated with information that can identify a living individual. Most states require informed consent for the use of fetal tissue in research. Accordingly, NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.

When obtaining primary human fetal tissue for research purposes, NIH expects grantees and contractors to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

The policy applies to all NIH-funded competing grant awards, non-competing grant awards, and R&D contracts issued after the date of this policy notice. This policy will be included in the terms and conditions of grant and cooperative agreement awards as well as contracts issued for research involving human fetal tissue. The policy also applies to NIH intramural research investigators.

Inquiries

For questions regarding a specific application or award, please contact the assigned NIH grants management specialist.

For questions regarding a specific contract proposal or award, please contact the assigned NIH contracting officer.

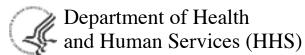
For general questions related to this policy, please contact:

Lyric Jorgenson, Ph.D. NIH Office of Science Policy Telephone: 301-496-9838

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